

6/18/07

**DRAFT Agenda - ASEAN Enhanced Partnership
Medical Devices Capacity Building Workshop
Hanoi, Viet Nam, July 30 – 31, 2007**

Sunday, July 29

6:00 – 7:30 pm **Welcome Reception**

Monday, July 30

8:30 - 9:15 **Introductory Session**

ASEAN Secretariat Speaker--Ms. Le Chau Giang, Senior Officer,
Standards and Conformance Unit, Bureau of Economic Integration and
Finance (confirmed)

Host Viet Nam Government Speaker (to be determined)

ASEAN Medical Device Harmonization Activities
Dr. M.S. Pillay, Ministry of Health, Malaysia; Chair of ASEAN ACCSQ
Medical Device Product Working Group, and Chair of the Asian
Harmonization Working Party (AHWP) (confirmed)

Welcome from GHTF Chair Larry Kessler, Director, Office of Science
and Engineering Laboratories, CDRH, U.S. FDA (confirmed)

Summary of Workshop Agenda – Stephen Berlinguette, International
Trade Specialist, Office of the Pacific Basin, U.S. Department of
Commerce (confirmed)

9:15 - 5:00 **Theme #1 – Building a Regulatory Infrastructure to Promote the
Access and Use of Medical Technology**

9:15 - 9:45 The Need for Flexible Medical Device Regulatory Regimes to Address the
Changing Nature of Medical Technologies
Speaker - Janet Trunzo, AdvaMed (confirmed)

9:45 - 10:15 Differences Between Pharmaceuticals and Medical Devices
Speaker - Michael Gropp, Vice President, Global Regulatory Strategy,
Medtronic, representing AdvaMed and Eucomed (confirmed)

10:15 - 10:30 Coffee Break

10:30 - 12:00 Case Studies - Establishing Flexible Regulatory Regimes

Moderator: Jeffrey Gren, Director, Office of Health and Consumer Goods, U.S. Department of Commerce (confirmed)

Panelists: 1) Dr. M.S. Pillay, Malaysia; (confirmed)
2) Mr. Yew Sin Wong, Singapore - (confirmed)
3) Dr. Monica M. H. Wong, Hong Kong - (confirmed)
4) Rita Maclachlan, Australia TGA (confirmed)
5) Laurent Selles, Deputy Head of Cosmetics and Medical Devices Unit, Enterprise and Industry Directorate-General, European Commission (confirmed)

12:00 - 12:15 Group Picture

12:15 - 1:15 Lunch

1:15 - 2:45 Panel Discussion - The Role of Accredited Persons/Conformity Assessment Bodies in the Regulatory Process and Establishing Confidence in Performance of Accredited Persons/Conformity Assessment Bodies

Moderator: Larry Kessler, U.S. FDA (confirmed)

Panelists: 1) Laurent Selles, European Commission (confirmed)
2) Alfred Kwek, Regulatory Scientist and Manager, Health Sciences Authority, Singapore (confirmed)
3) Yuwadee Patanawong - Thailand (invited)
4) Hwee Beng Wang - Malaysia (confirmed)
5) Paul Chan, General Manager Medical Business Unit, Asia Pacific UL International Limited - (confirmed)

2:45 – 3:15 Challenges to Regulators Due to Changing Medical Device Technologies, Rita Maclachlan, Australia TGA (confirmed)

3:15 - 3:30 Coffee Break

3:30 - 5:00 Panel Discussion - Addressing Medical Needs in ASEAN Countries Related to Aging Populations and the Growing Prevalence of Chronic Diseases and How these Trends will Drive the use of Medical Technologies

Moderator: Seow-Ping Goh - Johnson & Johnson Vietnam (confirmed)
Panelists: 1) Miang Chadaporn Tanakasemsub, Regional Regulatory Affairs Director, Asia Pacific, Bausch and Lomb (confirmed)
2) Dr. TC Khoo, Vice President, Strategic Medical Affairs, Johnson & Johnson Medical (confirmed)
3) Paul VanOstenberg, Joint Commission International, Managing Director for the Asia-Pacific Office (Singapore) (invited)

6:30 - 8:00 Reception

Tuesday, July 31

8:30 – 12:00 **Theme #2 - How to Grow a Medical Technology Sector at the National and Regional ASEAN Levels**

8:30 - 10:00 Panel Discussion – How to Grow a Medical Technology Sector at the National and Regional Levels and Protecting Intellectual Property and Stopping Counterfeiting Related to Medical Devices and Health Information Technology

Moderator: Janet Trunzo, AdvaMed (confirmed)
Panelists: 1) Dr. TC Khoo, Vice President, Strategic Medical Affairs, Johnson & Johnson Medical
2) to be determined
3) to be determined

10:00 - 10:15 Coffee Break

10:15 - 12:00 Panel Discussion – Case Studies – Successful Examples of Growing a Medical Technology Sector

Moderator: Brad Hossack, Boston Scientific (confirmed)
Panelists: 1) United States – Jeffrey Gren, U.S. Department of Commerce (confirmed)
2) Europe - Laurent Selles, European Commission (confirmed)
3) Australia - Rita Maclachlan, Australia TGA (confirmed)
4) Ireland - Brad Hossack, Boston Scientific (confirmed)
5) Singapore - (speaker to be determined)
6) Malaysia - (speaker to be determined)

12:00 - 1:00 Lunch

1:00 - 3:00 **Theme #3 - Possible Future Areas for Cooperation Under ASEAN Enhanced Partnership Relating to Medical Devices**

1:00 - 3:00 Panel Discussion - Possible Future Areas for Cooperation Under ASEAN Enhanced Partnership Relating to Medical Devices

Moderator: Michael Gropp, Vice President, Global Regulatory Strategy, Medtronic, Representing AdvaMed and Eucomed (confirmed)

- 1) Technology to Diagnose and Treat Primary Diseases/Infections, Pandemics, and Chronic Illness - Miang Chadaporn Tanakasemsub, Bausch and Lomb (confirmed)
- 2) Rural Healthcare/Telehealth, Jeffrey Gren, U.S. Department of Commerce (confirmed)
- 3) The Needs of Healthcare Providers, Seow-Ping Goh - Johnson & Johnson Vietnam (confirmed)
- 4) Healthcare Workers - Technology, Training, and Education Needs – Dr. TC Khoo, Vice President, Strategic Medical Affairs, Johnson & Johnson Medical (confirmed)
- 5) Integration of Information Technology, Quality and Patient Safety - Paul VanOstenberg, Joint Commission International, Managing Director for the Asia-Pacific Office (Singapore) (invited)

3:30 - 3:45 Coffee Break

3:45 – 5:00 **Theme #4 – Pulling it Together and Conclusion**

3:45 - 5:00 Wrap-Up, Conclusion and Future Activities

Moderators:

Jeffrey Gren, U.S. Department of Commerce (confirmed),
and

Dr. M.S. Pillay, Ministry of Health, Malaysia (confirmed)

- Summary of Workshop
- Development of Follow-up Activities and Next Steps
- How Medical Technology Activities in the ASEAN Region Relates to Activities in Other Regions
- Topics and Timing for Future Workshops

5:00 Adjournment